RECEIVED CENTRAL FAX CENTER AUG 0 9 2006



FACSIMILE COVER SHEET

Date:

August 9, 2006

To Examiner:

Alstrum Acevedo, James Henry

Group 1616

From:

Carolyn S. Elmore, Esq.

Registration No. 37,567

Fax Number:

(571) 273-8300

Subject:

Paper:

Second Petition Under 37 CFR 1.181

Docket No.: 2685.2046 US3

Applicants: Richard P. Batycky, et al.

Serial No.:

10/607,571

Filing Date: June 26, 2003

Number of pages including this cover sheet 9

Please confirm receipt of facsimile:

Yes <u>XX</u> No ___

Comments:

AF

Privileged and Confidential - All information transmitted hereby is intended only for the use of the addressec(s) named above. If the reader of this message is not the intended recipient or the employee or agent responsible for delivering the message to the intended recipient(s), please note that any distribution or copying of this communication is strictly prohibited. Anyone who received this communication in error is asked to notify us immediately by telephone and to destroy the original message or return it to us at the above address via first class mail.

Ø 002

AUG 0 9 2006

2685.2046 US3

Expedited Procedure under 37 CFR 1.116
Examining Group 1616

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Richard P. Batycky, Giovanni Caponetti, Mariko Childs, Elliot Ehrich,

Karen Fu, Jeffrey S. Hrkach, Wen-I. Li, Michael M. Lipp, Mei-Ling Pan and

Jason Summa

Application No:

10/607,571

Group No.: 1616

Filed:

June 26, 2003

C-----

Examiner: Alstrum Acevedo, James Henry

Confirmation No.:

6287

Title:

INHALABLE EPINEPHRINE

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:

Signature

Date

8-9

HOLLIE WAKEFIELD

Typed or printed name of person signing certificate

SECOND PETITION UNDER 37 CFR 1.181

Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This is the second petition filed under 37 CFR 1.181 in the above identified application. The first petition, timely filed on June 6, 2006 under 37 CFR 1.181. A copy of the first petition is attached together with the facsimile cover sheet and confirmation of facsimile transmission. Also enclosed is a confirmation executed by Ms. Hollie Wakefield that she did in fact execute the certificate on the June 6, 2006 Petition and fax the paper to the facsimile number identified on the facsimile cover sheet. The undersigned reviewed the status of the above identified patent application and discovered that the petition was not recorded in PAIR. As such, this paper is necessary. To ensure that this paper is forwarded to the correct individuals, it too is filed as a petition. Consideration of these petitions is respectfully requested.

Application No.: 10/607,571 Petition under Rule §1.181

Applicants hereby petition the Commissioner for Patents under 37 C.F.R. §1.181 to withdraw the finality of the office action mailed April 6, 2006 in the above-identified application.

In response to the first office action in the above-identified application dated September 9, 2005, Applicants amended the claims to incorporate a claim limitation of dependent claim 145 into independent claim 140. In response to Applicants' amendment and accompanying remarks, the Examiner withdrew all previous rejections and issued a final office action dated April 6, 2006, rejecting the claims under §§102 and 103 over new prior art cited not previously cited in the application. The Examiner also stated that Applicants' amendment necessitated the new ground of rejection citing MPEP §706.07(a).

In accordance with MPEP §706.07(a), "A second or any subsequent action on the merits in any application or patent involved in reexamination proceedings should not be made final if it includes a rejection, on prior art not of record, of any claim amended to include limitations which should reasonably have been expected to be claimed" [emphasis added]. In the present application, Applicants added the limitation of dependent claim 145 to independent claim 140 and canceled claim 145. Amended claim 140 is of identical scope to that of the previously presented claim 145 (now canceled). Clearly, an amendment to an independent claim that merely adds a dependent claim limitation present in a previously presented and examined claim set is expected particularly in view of the fact that the limitation was already specifically claimed in the previously presented and examined claim set. Clearly, such an amendment does not necessitate a new ground of rejection of at least amended claim 140. The finality of the rejection is improper under these circumstances. Applicants respectfully request that this petition be granted and that the finality of the Examiner's rejection in the Office Action be withdrawn.

As no decision on the first petition was received, an Amendment after Final Rejection was filed on July 20, 2006. The amendment was refused entry in the Advisory Action dated August 1, 2006. Applicants additionally petition the Director to direct the Examiner to enter the amendment. It is appreciated that in the event that the Finality of the Office action is removed, that the amendment submitted on July 20, 2006 will be entered. Nonetheless, in the event that the first petition is denied, it is respectfully requested that the amendment be entered.

The Amendment introduces into independent Claim 140 (directed to methods of administering particles containing epinephrine possessing specified physical characteristics) Claim 155 (limiting the method of administration to an inhalation to a single breath activated step),

Page 2 of 3

Application No.: 10/607,571 Petition under Rule §1.181

eliminating the need for Claims 151 and 154 of intermediate scope, and the dose of Claim 152. The Advisory Action recognizes that the amendment does not raise the issue of new matter or any other new issue. The reason for refusing to enter the amendment is that the amendments do not simplify or reduce the issues on appeal. This is simply not understood. How can an amendment that focuses the issues to a specified inhaler by a specified inhalation method not reduce the issues on appeal. Unless the amendment is entered, any appeal brief, examiner's answer and decision would need to independently consider the limitations of Claims 140, 151, 152, 154 and 155. Certainly, such an amendment is in compliance with 37 CFR 1.116.

No fee is believed to be due. Nonetheless, in the event that the USPTO determines that a fee is necessary, please charge the fees to Deposit Account No. 502807. Please charge any deficiency or credit any overpayment in the fees that may be due in this matter to Deposit Account No. 502807.

Respectfully submitted,

ELMORE PATENT LAW GROUP, PC

Carolyn S. Elmore

Registration No. 37567 Telephone: (978) 251-3509 Facsimile: (978) 251-3973

N. Chelmsford, MA 01863

Dated:

Ø 005

AUG 0 9 2006

2685.2046 US3

Expedited Procedure under 37 CFR 1.116

Examining Group 1616

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Richard P. Batycky, Giovanni Caponetti, Mariko Childs, Elliot Ehrich,

Karen Fu, Jeffrey S. Hrkach, Wen-I. Li, Michael M. Lipp, Mei-Ling Pan and

Jason Summa

Application No:

10/607,571

Group No.: 1616

Filed:

June 26, 2003

Examiner: Alstrum Acevedo, James Henry

Confirmation No.:

6287

Title:

INHALABLE EPINEPHRINE

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trudemark Office on:

(Datefula)
Signature

Date O-9-2000

HOLLIE WAKEFIELD

Typed or printed name of person signing certificate

PERSONAL STATEMENT BY HOLLIE WAKEFIELD

Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

I, Hollie Wakefield, of Elmore Patent Law Group, PC hereby personally attest that, on June 6, 2006, I signed the certificate of mailing appearing on the enclosed Petition Under 37 CFR 1.181 and transmitted the document by facsimile to the number stated on the Facsimile Cover Sheet. Respectfully submitted,

Hollie Wakefield

Tel.: (978) 251-3509 Fax: (978) 251-3973

N. Chelmsford, Massachusetts 01863

Date:

8/9/2006

Waterfield

Ø1006

AUG 0 9 2006 2685.2046 US3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Richard P. Batycky, Giovanni Caponetti, Mariko Childs, Elliot Ehrich,

Karen Fu, Jeffrey S. Hrkach, Wen-I. Li, Michael M. Lipp, Mei-Ling Pan and

Jason Summa

Application No: 10/607,571

Group No.: 1616

Filed:

June 26, 2003

Examiner: Alstrum Acevedo, James Henry

Confirmation No.:

6287

Title:

INHALABLE EPINEPHRINE

Copy to Client Date: 6/13/66

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:

Helee Water Date

Signature

HOLLIE WAKEFIELD

Typed or printed name of person signing certificate

PETITION UNDER 37 C.F.R. §1.181

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants hereby petition the Commissioner for Patents under 37 C.F.R. §1.181 to withdraw the finality of the office action mailed April 6, 2006 in the above-identified application.

In response to the first office action in the above-identified application dated September 9, 2005, Applicants amended the claims to incorporate a claim limitation of dependent claim 145 into independent claim 140. In response to Applicants' amendment and accompanying remarks, the Examiner withdrew all previous rejections and issued a final office action dated April 6, 2006, rejecting the claims under §§102 and 103 over new prior art cited not previously cited in the application. The Examiner also stated that Applicants' amendment necessitated the new ground of rejection citing MPEP §706.07(a).

Application No.: 10/607,571 Petition under Rule §1.181

In accordance with MPEP §706.07(a), "A second or any subsequent action on the merits in any application or patent involved in reexamination proceedings should not be made final if it includes a rejection, on prior art not of record, of any claim amended to include limitations which should reasonably have been expected to be claimed" [emphasis added]. In the present application, Applicants added the limitation of dependent claim 145 to independent claim 140 and canceled claim 145. Amended claim 140 is of identical scope to that of the previously presented claim 145 (now canceled). Clearly an amendment to an independent claim that merely adds a dependent claim limitation present in a previously presented and examined claim set is expected particularly in view of the fact that the limitation was already specifically claimed in the previously presented and examined claim set. Clearly such an amendment does not necessitate a new ground of rejection. The finality of the rejection is improper under these circumstances. Applicants respectfully request that this petition be granted and that the finality of the Examiner's rejection in the Office Action be withdrawn.

Please charge the fees to Deposit Account No. 502807 to cover the fees required for filing the indicated documents. Please charge any deficiency or credit any overpayment in the fees that may be due in this matter to Deposit Account No. 502807.

Respectfully submitted,

ELMORE PATENT LAW GROUP, PC

Darlene A. Vanstone

Registration No. 35,729

Telephone: (978) 251-3509 Facsimile: (978) 251-3973

N. Chelmsford, MA 01863

Dated: June 6, 2006

08/09/2006 16:38 FAX



RECEIVED **CENTRAL FAX CENTER**

FACSIMILE COVER SHEET

Date:

June 6, 2006

To Examiner:

James Henry Alstrum Acevedo

Group 1616

From:

Darlene A. Vanstone

Registration No. 35,729

Fax Number:

(571)273-8300

Subject:

Paper:

Petition Under 37 CFR 1.181

Docket No.: 2685.2046 US3

Applicants: Richard P. Batycky, et al.

Serial No.:

10/607,571

Filing Date: June 26, 2003

Number of pages <u>including this cover sheet</u> 3

Please confirm receipt of facsimile:

Yes X

No

Comments:

Privileged and Confidential - All information transmitted hereby is intended only for the use of the addressee(s) named above. If the reader of this message is not the intended recipient or the employee or agent responsible for delivering the message to the intended recipient(s), please note that any distribution or copying of this communication is strictly prohibited. Anyone who received this communication in error is asked to notify us immediately by telephone and to destroy the original message or return it to us at the above address via first class mail,

ST.	TIME	CONNECTION TEL/ID	SENDER	NAMR	NO.	MODE		PGS.	R	ESULT
06/01	11:18	011442075394299		· -	2633	TRANSMIT	ÉCM	2	OK	00,38
06/01	12:28	16177473970			2634	TRANSMIT	G3	3	OK	01'15
06/01	14:18	19782039223			2635	TRANSMIT	ECM		OK	01'57
06/02	13:29	15712738300			2636	TRANSMIT	ECM	22	OK	06'05
08/02	13:37	15712730140			2637	TRANSMIT	ECM	5	OK	02'00
06/02	14:19	ARIAD Finance			2638	TRANSMIT	ECM	2	OK	00'27
		16172252860								
06/05	11:49	HYBRIDON, INC			2639	TRANSMIT	ÉCM	2	OK	00'27
		16176795560						_		
06/05	13:09	16179517050			I	TRANSMIT	ECM		OK	00'45
06/06	12:34	01181669106735				TRANSMIT	ECM		OK	00'35
06/06	12:37	011441732450113				TRANSMIT	ECM		OK	00'32
06/06	12:39	01181669106735				TRANSMIT	ECM		OK	00'38
06/06	12:43	17035675519			1	TRANSMIT	ECM	3	OK	00'47
06/06	12:45	16135639869			2645	TRANSMIT	ECM	1	NG	00'48
									1	
06/06	12:47	16135639869			1	TRANSMIT	ECM		OK	02'07
06/06	12:50	01161392542770				TRANSMIT	ECM	4	OK	00'52
06/06	12:54	01161392542770			1	TRANSMIT	ECM		OK	01'23
06/06	12:58	01181669106735			t .	TRANSMIT	ECM		OK	00'27
06/06	17:01	15712738300			2650	TRANSMIT		0	NG	00'36
00 /00	4.7.00	,571071070			2653	TRANSMIT		ا ا	NG NG	00'00
06/06	17:07	15712718300			2002	IRANGMII		"		STOP
00/00	17.00	15710720200			2654	TRANSMIT	ECM	3	ок	00'54
	17:09	15712738300 011441732450113			1 -	TRANSMIT	ECM		ок	00'27
	17:22				L L	TRANSMIT	ECM	3	ок	01'04
	09:30	15712738300 15712738300				TRANSMIT	ECM	4	ок	01'0
	10:58				į.	TRANSMIT	ECM	43	f	16'42
	11:07	011442075394299 0118227537315			i i	TRANSMIT	ECM	1	OK	21'0
	11:29	0118227337313				TRANSMIT	ECM	ł	OK	07'3
	12:00	17035675519				TRANSMIT	ECM	44	ok	07'4
	12:15					TRANSMIT	ECM		OK	46'5
	12:29	16135639869				AUTO RX	ECM	1	OK	01'1
	13:17	0117959249540			2664	TRANSMIT	.,0.	1 -	NG	00.00
UQ/US	13:23	0117959249540			2004	IRANGIRA				STOP
06/00	13:24	01170959249543			2865	TRANSMIT		6	NG	00,00
00/00	13:24	01170939249345			2000	IRANOMIA		ľ		STOP
06/09	12.95	0117050240543			2886	TRANSMIT		۱ ،	NG	00'00
00/00	13:25	0117959249543			2000	IMMOMIT		ľ		STOP
06/08	13:30	01174952218885			2667	TRANSMIT	G3	0	NG	00'39
									0	
06/08	13:31	01174952218886			2668	TRANSMIT	G3	6	NG	04'3
		ļ							6	
06/08	[3:38	01174952218886			2669	TRANSMIT	EÇM	43	oκ	10'0
	19:59	0118227537315			2670	TRANSMIT	ECM	,	oĸ	05'4
	10:03	15712738300			2671	TRANSMIT	ECM	2	NG	00'2
		1				}			2	STOP
06/09	10:05	15712738300			2672	TRANSMIT	ECM	10	OK	02'1
	16:49	15712732885			2674	TRANSMIT	ECM	2	OK	00'4
	11:06	13017628663			2675	TRANSMIT	ECM	1	OK	00'1